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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 849,597	05 07 2001	Han Oh Park	024018 0111	8892

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04 17 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,597

Applicant(s)

PARK ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 14) filed on February 6, 2003 has been entered.

Response to Arguments

2. Applicant's response to the office action (Paper No.14) is fully considered and deemed persuasive.

3. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicant's arguments with respect to claims 1, 3, 5-12 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejections necessitated by Amendment

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 7, 12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Riley et al. (Nucleic Acids Res., Vol. 18, No. 10, pp. 2887-2890, 1990).

With reference to the instant claim 3, Riley et al. teach a process for selective amplifying DNA of which base sequence is completely unidentified, wherein Riley et al. disclose that the method comprises (i) digesting a DNA into fragments which have the single-stranded cohesive ends by using a restriction enzyme (see page 2887, column 2, paragraph 3); (ii) preparing hairpin loop adapters (vectorette oligonucleotide linker) which have single-strand cohesive ends (see

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page 2888, Fig. 1, column 1, paragraph 1): (iii) ligating the DNA fragments with the hairpin loop adapter by using DNA ligase (see page 2888, column 1, paragraph 1); (iv-vi) removing unligated DNA fragments and hairpin loop adapters and eliminating hairpin loop structure from DNA fragments, by using a DNA polymerase with exonuclease activity and amplifying the DNA fragments by using the DNA polymerase and a primer which can combine complementarily to a residual sequence from the adapter (vectorate over hang specific primer) (see page 2888, column 1, paragraph 1, column 2, paragraphs 1-2, Fig. 1).

With reference to the instant claims 7, 12, and 14, Riley et al. teaches that the method comprises (i) ligase as T4 DNA ligase (see page 2888, column 1, paragraph 1); DNA polymerase as Taq DNA polymerase (see page 2888, column 2, paragraph 1); The hairpin loop adapters comprise combination of four nucleotides (see page 2889, column 1, lines 1-5). Thus the disclosure of Riley et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-6, 8-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley et al. (Nucleic Acids Res., Vol. 18, No. 10, pp. 2887-2890, 1990) and in view of Kaufman et al. (US 6,383,754).

Riley et al. teach a process for selective amplifying DNA of which base sequence is completely unidentified, wherein Riley et al. disclose that the method comprises (i) digesting a DNA into fragments which have the single-stranded cohesive ends by using a restriction enzyme (see page 2887, column 2, paragraph 3); (ii) preparing hairpin loop adapters (vectorette oligonucleotide linker) which have single-strand cohesive ends (see page 2888, Fig. 1, column 1, paragraph 1); (iii) ligating the DNA fragments with the hairpin loop adapter by using DNA ligase (see page 2888, column 1, paragraph 1); (iv-vi) removing unligated DNA fragments and hairpin loop adapters and eliminating hairpin loop structure from DNA fragments, by using a DNA polymerase with exonuclease activity and amplifying the DNA fragments by using the DNA polymerase and a primer which can combine complementarily to a residual sequence from the adapter (vectorate over hang specific primer) (see page 2888, column 1, paragraph 1, column 2, paragraphs 1-2, Fig. 1). Riley et al. also teaches that the method comprises (i) ligase as T4 DNA ligase (see page 2888, column 1, paragraph 1); DNA polymerase as Taq DNA polymerase (see page 2888, column 2, paragraph 1); The hairpin loop adapters comprise combination of four nucleotides (see page 2889, column 1, lines 1-5). However, Riley et al. did not teach removing hairpin loop adapters using an alkaline phosphatase or RNase or a single strand specific exonuclease.

Kaufman et al. teach a method for producing binary encoded sequence tags, wherein Kaufman et al. teach that the method comprises (i) cleaving DNA with type IIS restriction endonucleases thereby generating sticky ends; ligating offset adapters with sticky ends (see column 9, lines 5-67, column 10, lines 1-33); single-strand of the linkers comprise random combination of 4 nucleotides (see column 11, lines 63-67, column 12, lines 1-7); use of exonuclease digestion and removal on non-ligated tag-hairpins with alkali treatment (see column 44, lines 25-31, column 53, line 55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of selectively amplifying any fragment generated by restriction enzyme, including adapters specific to fragment ends as taught by Riley et al. with the correction of ligated products as taught by Kaufman et al., which is applicable to eliminate hairpin loop structures because Kaufman suggests that "the set of binary sequence tags produced from a nucleic acid sample using particular cleaving reagents and adaptors will produce characteristic sets of binary sequence tags" The method allows a complex sample of nucleic acid to be cataloged quickly and easily in a reproducible and sequence-specific manner. An ordinary practitioner would have been motivated to combine the method of selective amplification of DNA fragments as taught by Riley et al. with the use of mechanism for controlling cohesive ends by cleaving reagents as taught by Kaufman et al. removal of hairpin loop structures from the ligated DNA fragments would be advantageous in reducing background noise and enhancing the reproducibility and quick isolation of selective PCR amplification products and thereby benefit, developing a method of amplification with increased sensitivity and specificity.

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Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
April 11, 2003



JEFFREY FREDMAN
PRIMARY EXAMINER